CASE AUTH/1846/6/06 *NO BREACH OF THE CODE*

FORMER EMPLOYEE v MERCK SHARP & DOHME

Memorandum and briefing document

A former employee of Merck Sharp & Dohme complained about internal memoranda relating to the matters at issue in Case AUTH/1814/3/06 and a field force briefing document concerning the creation of partnership development managers (PDMs) by Schering-Plough as part of a Schering-Plough/Merck Sharp & Dohme co-promotion agreement.

The complainant provided copies of two memoranda sent to all of Merck Sharp & Dohme's sales teams involved in the promotion of Cozaar (losartan). The complainant noted that the memorandum sent from the cardiovascular business unit stated *inter alia*, that Merck Sharp & Dohme considered that the audit protocol (at issue in Case AUTH/1814/3/06) complied with the Code.

The complainant considered that this statement was remarkable as it clearly contradicted Merck Sharp & Dohme's acceptance of the likely breach of the Code on 29 March 2006. The complainant alleged that the memorandum failed to maintain high standards of behaviour when telling internal audiences about matters related to alleged breaches of the Code.

The complainant also provided a briefing document that was issued to relevant field force members regarding the creation of PDMs. The scope and responsibilities of the PDM's role appeared to be that of a provider of medical and educational goods and services as opposed to that of a representative. Accordingly, the complainant was surprised and concerned to see that the PDM role also appeared to have commercial responsibilities. The complainant questioned whether the stated objectives of the PDM role were consistent with the Code.

The Panel noted Merck Sharp & Sharp's submission that the reference in the memorandum from the cardiovascular business unit was to the audit protocol and to the proformas which, as noted in Case AUTH/1814/3/06, had been revised to comply with the Code and reissued in September 2005. The Panel considered that the proformas referred to could be those formally certified by Merck Sharp & Dohme as opposed to those which had not been approved for use and which had been in question in

Case AUTH/1814/3/06. It was very important that correspondence about the proformas should be clear about which document was being referred to. The memorandum at issue was not entirely clear about which proformas were referred to but the Panel did not consider that it was inconsistent with Merck Sharp & Dohme's response in Case AUTH/1814/3/06. No breach of the Code was ruled.

With regard to the briefing document for the PDM role, the Panel did not consider there was any evidence that the role as described in the briefing document was in breach of the Code. It appeared that the role was a commercial/promotional one rather than providing medical and educational goods and services. The Panel considered that the Merck Sharp & Dohme briefing document was not inconsistent with the Code. No breach of the Code was ruled.

A former employee of Merck Sharp & Dohme Limited complained about internal memoranda relating to the matters at issue in Case AUTH/1814/3/06 and a field force briefing document concerning the creation of partnership development managers (PDMs) by Schering-Plough Ltd as part of the Schering-Plough/Merck Sharp & Dohme co-promotion of Ezetrol (ezetimibe) and Inegy (ezetimibe/simvastatin).

COMPLAINT

The complainant provided copies of two memoranda dated 2 and 8 May 2006 sent to all of Merck Sharp & Dohme's sales teams involved in the promotion of Cozaar (losartan). The memoranda had recently been brought to the complainant's attention by an ex-colleague within Merck Sharp & Dohme's field force.

The complainant referred to the memorandum sent from the cardiovascular business unit and dated 2 May 2006 which stated *inter alia*:

> 'MSD believes that … audit protocol complies with code guidance regarding audit activity save for the BHS ABCD guidance which was has [sic] been amended in light of a previous case to reflect accurately the original BHS guidance.'

The complainant noted that Merck Sharp & Dohme's response to the complaint in Case AUTH/1814/3/06 regarding the nurse audit programme, dated 29 March 2006, stated the following in respect of the Hypertension and Type 2 diabetes proformas that were a central component of Merck Sharp & Dohme's implementation of the nurse advisor programme:

> 'They were not reviewed internally and we believe that they breach Clause 18.1 of the Code. We would like to take this opportunity to apologise to the Authority that these proformas were sent out in this form for use by representatives. We are conducting an internal investigation into the matter and once that investigation is completed disciplinary action will be taken if appropriate.'

The complainant noted that given that the author of the memorandum reported directly to the managing director and in light of the seriousness with which the company claimed to view adherence to the Code, the statement to the entire field force that 'Merck Sharp & Dohme believes that the … audit protocol complies with the code guidance regarding audit activity…' was remarkable when it clearly contradicted the company's acceptance of the likely breach of Clause 18.1 on 29 March 2006. The complainant alleged that the memorandum was in breach of Clause 9.1 of the 2003 Code in that it failed to maintain high standards of behaviour when communicating to internal audiences on matters pertaining to alleged breaches of the Code.

The complainant also provided a briefing document that was recently issued by Merck Sharp & Dohme to its relevant field force members in relation to the creation of partnership development managers (PDMs) as a component of Schering-Plough/Merck Sharp & Dohme's co-promotion of Inegy and Ezetrol. The scope and responsibilities of the PDM role appeared to be that of a provider of medical and educational goods and services as distinct from that of a medical/generic sales representative. Accordingly, the complainant was surprised and concerned to see that the PDM role also appeared to have commercial responsibilities:

> 'PDMs will build partnerships in key accounts and local clinical networks, working alongside the existing Regional Sales teams. The PDM will identify commercial opportunities and develop partnerships across key accounts and their clinical and managerial networks resulting in incremental market share growth for Schering-Plough brands.
>
> Identify and realise commercial opportunities (patient identification and management). Work with commissioning locality groups to cement the environment for SP products.'

The complainant questioned whether the stated objectives of the PDM role were consistent with the Code. The complainant explained that the PDM initiative and roles were attributable to Schering-Plough. However, the briefing document had been subject to Merck Sharp & Dohme's medico-legal review process, as the case for all bulletins provided by Merck Sharp & Dohme to its field force. The purpose of this bulletin was to ensure that Merck Sharp & Dohme staff involved in the co-promotional venture with Schering-Plough were fully apprised of activities undertaken by its partner company. The complainant explained that he raised his concerns about the potential Code compliance of the Schering-Plough PDM role because the bulletin had been subject to Merck Sharp & Dohme's medico-legal review process which suggested that the company saw no issue with the appropriateness of the PDM role.

When writing to Merck Sharp & Dohme the Authority asked it to respond in relation to Clauses 2, 9.1, 15.9, 18.1 and 18.4 of the Code.

RESPONSE

Merck Sharp & Dohme refuted the allegation that the memorandum from the cardiovascular business unit was inconsistent with Merck Sharp & Dohme's response to Case AUTH/1814/3/06.

Merck Sharp & Dohme submitted that its response to the previous case had referred to the original

proforma which formed part of the complaint. The memorandum from the cardiovascular business unit clearly referred to the revised proforma, issued in September 2005 and to which reference was made in the response as well. Merck Sharp & Dohme was confident that the revised proformas were consistent with the Code. Accordingly Merck Sharp & Dohme submitted that this allegation had no substance.

Merck Sharp & Dohme noted that the complainant had also asked the Authority to consider whether the stated objectives of the PDM role were consistent with the Code. As the complainant acknowledged, the PDM was a Schering-Plough role. The briefing document in question was circulated by Merck Sharp & Dohme to staff in order that they would better understand the work undertaken by PDMs, with whom they would be working to further the commercial aims of the partnership. So far as Merck Sharp & Dohme was aware, there was no prohibition under the Code of jobs which encompassed both service provision and overt selling; the two must however be kept distinct in terms of actual delivery, hence representatives must not offer both the service and promote at the same visit. Merck Sharp & Dohme submitted that the PDM role was clearly a commercial one and did not seem to involve providing '…..medical and educational goods and services,' as alleged by the complainant. In any event, there was nothing in the document which supported the complainant's view that the role was not consistent with the Code. Merck Sharp & Dohme submitted that if the Authority had specific questions regarding the job and its responsibilities, it respectfully suggested that they might like to pose them to Schering-Plough Ltd.

Merck Sharp & Dohme trusted therefore that the above would satisfy the Panel that the company had not engaged in any activities which breached the Code and in particular Clauses 2, 9.1, 15.9, 18.1 and 18.4.

PANEL RULING

The Panel noted Merck Sharp & Sharp's submission that the reference in memorandum at issue was to the APMS audit protocol and to the proformas which, as noted in Case AUTH/1814/3/06, had been revised to comply with the Code and reissued in September 2005. The Panel considered that the proformas referred to could be those formally certified by Merck Sharp & Dohme as opposed to those which had not been approved for use and which had been in question in Case AUTH/1814/3/06. The complainant's quotation from Merck Sharp & Dohme's response to Case AUTH/1814/3/06 referred to these 'unapproved' proformas which the company submitted had been created by the Cozaar marketing team. It was very important that correspondence about the proformas should be clear about which document was being referred to. The memorandum on 2 May stated that the audit was suspended and then referred to the representative practice proformas. The memorandum was not entirely clear about which proformas were referred to but the Panel did not consider that the memorandum was inconsistent with Merck Sharp & Dohme's response in Case AUTH/1814/3/06. Thus the Panel ruled no breach of Clause 9.1 of the Code.

With regard to the briefing document for the PDM role, the Panel did not consider there was any evidence that the role as described in the briefing document was in breach of the Code. It appeared that the role was a commercial/promotional one rather than providing medical and educational goods and services. The Panel considered that the Merck Sharp & Dohme briefing document was not inconsistent with the Code. No breaches of Clauses 15.9, 18.1 and 18.4 of the Code were ruled.

Complaint received **1 June 2006**

Case completed **5 July 2006**